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IN THE UNITED STATES PATENT & TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Applicant: Marvin L. Schilling et al
Serial No: 09/964,120
Filed: 09-25-2001
For: Method for Producing Biologically Active Products
10 Group Art Unit: 1616 Examiner: Sharmila S. Gollamudi

Hon. Commissioner of Patents
& Trademarks,
Washington, D.C. 20231

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Reply Brief under 37 CFR 1.193(b)(1)

In response to the Examiner's Answer appellants request that the Board
20 consider the following arguments.

The examiner has rejected appellants' claims over the combination of Moore
in view of Luck and further in view of Steffan. The examiner admits that the Moore
reference does not teach appellants' claimed use of massive amounts of salt during the
25 heat drying of the collagen II containing cartilage in order to preserve the
physiological and remedial properties of the cartilage.

The examiner has cited the Luck et al reference to support the argument that it
would be obvious to add such salt. Luck relates to the sterilization of proteins using
30 microwaves such as are available in a microwave oven to sterilize the protein in such
a way as to retain the physiological properties of the protein. Contrary to the position
of the examiner the retention of physiological properties during drying is not a facet
of the invention disclosed. Although Luck discloses drying of the protein, the
retention of the physiological properties during drying is not a problem since it is

accomplished by lyophilization and not through heat drying which is the method disclosed by Moore. Lyophilization is the removal of water from the solid phase, i.e., ice, whereas heating as practiced by Moore is the removal of water in the liquid stage. What affects sublimation has not been shown to be equivalent to what affects vaporization. No motivation has been shown by the examiner as to why a person skilled in the art would look to the sublimation of water at very low pressures from the solid state to prevent the degradation proteins when heated to vaporize water.

The temperature ranges cited by the examiner in connection with the drying of proteins in Luck apply to the microwave treatment and not the drying step. The patentees do mention lyophilization of a sample at 30° C, which is room temperature, in the example. However, the examiner ignores the fact that the drying is of a frozen sample and since the patentees define the drying as "lyophilization", it must be assumed that the sample stays frozen during the drying process.

More importantly there is no illustration of the use of salt in the patent. There is only a single sentence in the entire reference that mentions the word salt. The sentence reads as follows:

"The protein is substantially dehydrated, either free or in combination with salts, which are *adventitiously* present in the aqueous medium". (Emphasis added)

The term "adventitiously" according to Webster's Dictionary means "coming from another source" or "not inherently present". In conjunction with the term "present" namely as in "adventitiously present" the term must mean that the salt was present in the aqueous medium before the drying step as a result of some other prior step. Thus the logical meaning of the term is that the presence of salt does not interfere with the lyophilization of the protein and that no salt is added specifically for the drying step. There is no disclosure of any interaction between the salt, the protein or the ice and there is no suggestion that any advantages could flow from the presence of the salt in preserving the biological properties of protein. Nor is it apparent that there is any physical benefit from the presence of salt during lyophilization. There is no suggestion in the reference that any advantage could be achieved if the protein is

lyophilized in the presence of a salt anywhere else in the patent. The example and the remainder of the patent disclose only lyophilization as the specific means of drying without any disclosure or suggestion of the use of a salt.

5 The examiner apparently misreads the word adventitiously as advantageously. Even aside from the dictionary meaning such an interpretation is not supported by the specification. For if it were, best mode requirement would have required the patentees to disclose the use of salt in the actual embodiments of the invention such as the examples. Since such is not disclosed there is no suggestion to deliberately add
10 salt to the aqueous medium.

 Thus the reference does not disclose drying by means of heating and does not contain any suggestion as to the nature of the salt or the amount of salt. At most therefore the reference gives only a very general suggestion that the presence of salt is
15 not deleterious but does not provide any suggestion that the presence of salt could have a beneficial effect. In the decision of In re Roemer, 258 F.3d 1303, 59 USPQ 1527 (Fed. Cir. 2001) the Court held that a reference giving only the general guidance is insufficient to suggest an invention directed to specific features. Here there is not even such a clear suggestion. Thus here there is no suggestion that any advantage
20 could be obtained if an ionic salt were to be added to the protein during the drying step. On the contrary what the reference teaches is that such does not make any difference and thus leads away from the use of ionic salt during the drying of the protein even if the drying process of the reference, i.e., lyophilization could be considered to be the equivalent of the heating employed by Moore or appellants.
25 Clearly the examiner has given this solitary teaching of the reference an import inspired by appellants' own teaching. In In re Dembiczak, (175 F.3d 994, 999, 50 USPQ2d 1225, 1232 (Fed.Cir. 1999)) the Court stated:

30 “Our case law makes clear that the best defense against the subtle but powerful attraction of hindsight based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.”

Appellants submit that the combination fails to suggest that the addition of salt during the drying step improves the retention of the physiological properties of the cartilage and that hence the claims are patentable.

5 The examiner admits that the Luck reference fails to disclose or suggest the concentrations of the salt employed in appellants' invention. The examiner relies on the Steffan to supply that missing element (page 5, lines 19-21). Yet at the same time the examiner acknowledges that the same reference fails to disclose the amount of salt employed by appellants (page 8, 15-18). Thus the reference fails to add anything to
10 the other references and hence fails to make the claimed invention obvious.

 The examiner also admits that the Steffan teachings are substantially different from Luck and Moore and "does not teach an edible product". However, the differences go far beyond that. Thus Steffan relates to the making of surgical fibers
15 from a collagen I material such as Achilles tendons taken from a calf. In that process Steffan first treats the material with an alkali base to chemically convert (saponify) the material and then with an acid to neutralize the resulting modified collagen. Then follows a mechanical treatment in which the collagen comprising the fibers isolated from denatured collagen and other components and partially dehydrated (column 3
20 lines 5-16). Thereafter the partially dried product is treated with salt and water (Column 5, lines 3-7). The salt is stated to aid in the extraction of water from the collagen. Since such is added in the presence of water it is clear that the product is not dried. Excess water is then mechanically removed. The actual drying of the product is obtained by using organic solvents, i.e., azeotropic distillation, as disclosed
25 in column 4, lines 1-5.

 Thus Steffan does not in any way attempt to preserve the physiological properties of collagen, which is the purpose of Luck and appellants' claims. Luck employs lyophilization to remove water, which involves vaporization of the water
30 from a solid, whereas Steffan relates to separation of water as a result of differences in concentration in the liquid phase. Nothing suggests that the lyophilization taught in Luck could be improved by the addition of salt. The examiner has taken the dehydrating step of Steffan out of context in order to combine such with the teachings

of Luck. Thus there is no objective evidence and hence motivation to support the combination. (In re Fine 837 F2d 1071, 5 USPQ2d 1596 (Fed.Cir. 1988), In re Jones 958 F2d. 347, 21 USPQ2d 1941 (Fed.Cir. 1992). Thus there is no basis for the combination.

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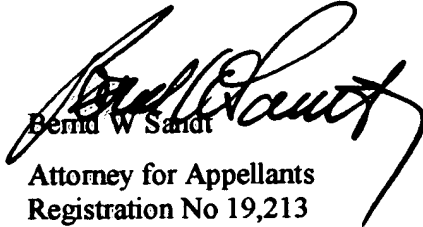
Furthermore the examiner does not refute appellants' argument that, even if the combination can be sustained, that the reference fails to teach the amount of salt employed in appellants' claims which further supports the patentability of the claims.

10 The examiner has further rejected appellants' claims over the combination of Moore and Japanese patent 590025637 (JP). The Japanese patent relates to preparing salted scallops. It contains no reference to collagen II. In the process salt is added to scallops to extract some water from the scallops. It is not clear that any water is removed rather than merely transferred from the scallops to the salt, which remains
15 with the scallops. In the final product a substantial number of other components are combined with the scallops to obtain a product which will result in the decomposition of proteins of the scallops to provide an improved taste.

 There is no suggestion to prepare a dry product or that the addition of salt will
20 cause physiological properties to be preserved. Both Moore and appellants employ heating as the means of drying the product and appellants employ the salt to preserve the physiological properties of the collagen II-containing cartilage during the heating process. There is no suggestion in JP that salt can improve the drying process when heat is used to remove the water or that salt will preserve physiological properties.
25 Looking fairly at the reference there is no objective evidence to combine the references. The products are different, the purpose of the salt addition is different and the methods of dehydrating the products are different. There is no motivation for a person skilled in the art to look to JP to modify the Moore reference.



Appellants submit that the appealed claims patentably distinguish over the references cited by the examiner and that the rejection of the claims should be reversed and the claims held allowable.


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